

A Newsletter of the Pharmacy Examining Board

July 2010

The Pharmacy Examining Board (PEB) consists of the following members.

Timothy Boehmer (Neenah)
Amy Mattila (Washburn)
Pamela Phillips (Secretary – Green Bay)
Suzette Renwick (La Crosse)
Jeanne Severson (Chair – Cottage Grove)
Jason Walker-Crawford (Vice Chair –
Cambridge)
Gregory Weber (Brown Deer)

The dates and times of Board meetings are announced on the DRL website at www.drl.wi.gov

Administrative Staff:

John Lease, Division Administrator Nora Wilson, Bureau Director Michele Miller Hayes, Legal Counsel Michelle Solem, Bureau Assistant

Executive Staff

Celia Jackson, Secretary Barbara Wyatt Sibley, Deputy Secretary Hector Colon, Executive Assistant

Biographies:

Go to: www.drl.wi.gov

In This Issue
Message from the Board1
Message from the Secretary1-2
DRL Improvements/Initiatives
NEW WI Law - Donation of Drug Samples3
New Laws
Administrative Rules3-4
DHS Variance Pandemic Influenza4
DEA Update4
Board Orders and Disciplines4-5

MESSAGE FROM THE BOARD

Staffing and Member Update

Nora Wilson is the new Bureau Director serving the Wisconsin Pharmacy Examining Board. Nora is a graduate of the UW-Madison Law School and was previously working in the DRL Division of Enforcement as a Law Clerk. In addition to her experience with the Agency, Nora has a well-rounded background in governmental work at a local and state level. Nora looks forward to working with the Pharmacy Examining Board and the pharmacists and pharmacy staffs of Wisconsin.

Michele Miller Hayes is the new Legal Counsel serving the Wisconsin Pharmacy Examining Board. Michele has 19 years of legal experience, 16 of which have been in a health-related practice. She worked six years in private practice both prosecuting and defending personal injury claims. She also spent almost 10 years at Wisconsin Physician Services Insurance Company defending health insurance claims and handling employment law matters. Michele looks forward to working with the Pharmacy Examining Board and the pharmacists and pharmacy staffs of Wisconsin.

Professional Board members Jeanne Severson, Jason Walker-Crawford, Greg Weber and public member Pamela Phillips were each reappointed by Governor Doyle and recently confirmed by the State Senate to serve another four year term.

SECRETARY'S MESSAGE

On behalf of the Department of Regulation and Licensing (DRL), I am pleased to contribute to this edition of the Pharmacy Examining Board Regulatory Digest. I've had the privilege of serving as Secretary for the past five years and, in all of my outreach efforts the one issue raised consistently by our licensees, across all professions, is the return of the Digest. This is one of the most important ways for us to remain connected. There are constantly new rules, new bills in the legislature and new practices within your profession that you need to be informed about.

In the summer of 2008, DRL staff worked with members of our boards to explore how we could improve customer service to our various constituencies. The Regulatory Digest was one of the top priorities identified to reach out to With the challenges in the state licensees. budget and the economic downturn, we have concluded that the most prudent way for us to be in communication is by distributing the digest electronically. The costs of hard copies and mailing put a tremendous strain on our resources resulting in the digest being one of the services that was cut. We hope that you will keep us updated on your current e-mail address so that you can receive your digest timely.

Technology has opened the door for many new ways of improving services. You can now print your license with our e-credential system; we have purchased equipment that allows us to do live meetings for our board members; our website has recently been redesigned to be more user-friendly and our integration of credentialing and enforcement systems is complete.

We have restructured our enforcement division and put in place a plan to resolve complaints more timely, we have been working on a plan to address the multitude of practice questions that we receive on a regular basis, and we have been hosting board meetings around the state to reach out to our licensees.

While we recognize that we have a ways to go, we have turned a corner. We welcome your

ideas, suggestions and comments on how to be in better communication with you in the practice of your profession.

Thank you, Secretary Celia Jackson

DRL IMPROVEMENTS/INITIATIVES

E-Credential (effective July 1, 2009)

E-Credential is the new way you will receive your credential. You will no longer have to wait for the DRL to mail a credential when you renew on-line. Instead, you will be able to print your own full color credential from your computer as soon as DRL processes your renewal. DRL will alert you by e-mail when your credential is available to be printed. Follow the link in the e-mail to a secure place on-line where you can print your credential. The new process will make it easy to update and print an official credential that reflects current information if you have a change of name or Decorative certificates are address. available. For more information, see the DRL's E-Credential FAQs and answers:

http://drl.wi.gov/faq_que_list.asp?fid=120&locid=0

Impaired Professional Procedure (IPP)

Work is underway to reform and improve the DRL's IPP program. IPP allows chemically dependent professionals to admit they have a problem and receive treatment for their addictions, without losing their professional credential. In 2009, DRL Secretary Celia Jackson appointed a task force to review the IPP program. DRL is packaging the task force's recommendations in a comprehensive revision of Wisconsin Administrative Code RL 7, which relates to IPP.

Division of Enforcement (DOE)

Last fall, the DRL announced the goal to close 90% of complaints opened for investigation within 18 months.

<u>NEW WISCONSIN LAW – DONATION OF</u> DRUG SAMPLES

Effective March 18, 2010, 2009 Wisconsin Act 142 adds an exception to the definition of wholesale distribution for donations of drugs and supplies and expands the previous cancer and chronic diseases repository to cover all donated drugs and supplies. Donations may be made to participating medical facilities and pharmacies and will be distributed to other eligible medical facilities or pharmacies for use under the program. Criteria for donations to the program are set out in 255.056 (3), Wisconsin Statutes. Dispensing priority will be to patients who are uninsured or indigent, but will allow dispensing to others if uninsured or indigent patients are not available.

NEW LAWS

2009 Wisconsin Act 362 (directing the PEB to create a program to monitor the dispensing of prescription drugs, i.e., Prescription Drug Monitoring Program for controlled substances). The program must do all of the following: 1) require a pharmacist, physician, advanced practice nurse, dentist or optometrist to generate electronic record documenting controlled dispensing of substance a prescription and to deliver the record to the Board (PEB), unless the prescription is administered directly to a patient; 2) identify data elements to be contained in such a record with a goal of maximizing the ability to share such information with other states; 3) specify to whom and under what circumstances such a record may be disclosed; 4) specify a format and deadline for delivery of such a record to the Board; and 5) specify a penalty for a failure to comply with program requirements.

The bill requires DRL to apply for certain federal grants to establish and operate the program. The writing of rules to implement the legislation may not begin until funding is received. If the Department fails to obtain federal funding before January 1, 2015, the bill is void.

2009 Wisconsin Act 280 (expedited partner therapy or EPT). This bill allows a physician, physician assistant, or certified advanced practice nurse practitioner to provide EPT. The bill defines EPT as prescribing, dispensing, or furnishing to a patient an antimicrobial drug to be used by a sexual partner of the patient to treat a chlamydial infection, gonorrhea, or

trichomoniasis without physical examination of the sexual partner. A prescription order for an antimicrobial drug prescribed for EPT must include the name and address of the patient's sexual partner, if known, or the words "expedited partner therapy" or "EPT" in boldface capital letters.

Under the bill, the DHS must prepare an information sheet that includes information about sexually transmitted diseases and their treatment and about the risk of drug allergies and prescribers are to give it to the patient with the request that the patient give it to their sexual partner.

The bill permits a pharmacist to dispense an antimicrobial drug to a patient upon receipt of a prescription order from a practitioner providing EPT. The bill exempts a pharmacist who dispenses an antimicrobial drug for EPT from civil liability for injury to or the death of a patient's sexual partner unless an act or omission of the pharmacist involves reckless, wanton, or intentional misconduct.

ADMINSTRATIVE RULES

Administrative Rule Change – Elimination of Practical Examination Requirement

Effective November 1, 2009, the Board eliminated Phar 4.02 (2), the practical examination requirement, also known as the consultation exam. Wisconsin's practical exam content is addressed by the two national exams, NAPLEX and MPJE. Eliminating the examination requirement removes a barrier and expedites licensure. Wisconsin became the 47th state to not require a state exam as a condition for licensure.

New Administrative Rule – Operation of Remote Dispensing Site

2007 Wisconsin Act 202, effective April 15, 2008, provided an exception to the general requirement that pharmacists dispense prescriptions drugs only at licensed pharmacies. Under the exception, a pharmacist may dispense at a "remote dispensing site" location, which is not, by definition, licensed as a pharmacy.

Effective April 1, 2010, Phar 7.095 sets forth the process and procedures for establishing and operating a remote dispensing site. DRL Form #2874 PEB titled, "Remote Dispensing Site Notice" must be submitted to the Board 30 days prior to opening. It is a notice requirement only; approval is not required.

Revised Administrative Rules Effective 6/1/2010

Wis. Admin. Code § PHAR 6.08, Security "A pharmacy shall have a centrally monitored alarm system in the pharmacy. A security system or plan that does not utilize a centrally monitored alarm system may be used if reviewed by and prior approval is obtained from the board."

Wis. Admin. Code § PHAR 8.12 (2) (b) "The prescription order is written for a schedule II controlled substance for a patient who resides in a long term care facility, or who meets the eligibility requirements for placement in a long term care facility, but elects to reside at home, and is transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile."

DHS VARIANCE PANDEMIC INFLUENZA – PATIENT AGE REQUIREMENT

On March 11, 2010, the Board extended DHS' variance allowing qualified pharmacists and pharmacy students to administer 2009 H1N1 influenza virus vaccine to patients 10 years of age or older. The other requirements of Wisconsin Statute 450.035 remain in effect.

DHS' variance will expire June 10, 2010 unless an extension is requested and granted.

DEA UPDATE

• On March 31, 2010, the DEA published its interim final rule on electronic prescriptions for controlled substances in the Federal Register. The effective date is June 1, 2010 (pending Congressional review).

The DEA is revising its regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations will also establish rules for pharmacies relating to receiving, dispensing, and archiving these electronic prescriptions. These regulations are in addition to, not a replacement for, existing rules.

Several pharmacy organizations, e.g., APhA and ASCP have provided a synopsis of the key requirements of the extensive regulations (83 pages).

• The DEA Milwaukee District Office has received several contacts from local police and county sheriff's departments concerning armed robberies and incidents of diversion at pharmacies, which have not been reported to the DEA (DEA Form 106, "Report Theft or Loss of Controlled Substance").

Phar 8.02 (3) (f) states "In any instance that a pharmacy, practitioner or other DEA registrant authorized to possess controlled substances is required to file with the DEA a report of theft or loss of controlled substances, the pharmacy, practitioner, or other DEA registrant shall also send a copy to the board within two weeks of filing with the DEA."

BOARD ORDERS & DISCIPLINES

April 2010

Allan T. Mailloux – Pharmacist, Oregon, WI The Pharmacy Examining Board reprimanded Allan T. Mailloux, R.Ph., and limited his license for his disorderly conduct conviction that came about after he exposed his genitals to people in several vehicles. He voluntarily underwent a psychological evaluation. Limitations include, but are not limited to, continued treatment by a Board-approved therapist at least once per month. Both his therapist and his supervisor must submit quarterly reports on his progress. Mailloux's license is further limited in that he may not practice as a pharmacist in a setting where he would have unsupervised access to female patients. The Board ordered Mailloux to pay costs of \$500.

Dated: April 7, 2010

http://online.drl.wi.gov/decisions/2010/ORDER 0000136-00004812.pdf

Lloyd G. Schaefer – Pharmacist, Green Bay, WI

The Pharmacy Examining Board reprimanded Lloyd G. Schaefer, R.Ph., and limited his license for obtaining identifying information of pharmacy clients for his personal benefit in the course of leaving employment to maintain a business relationship with the consumers. The Board has ordered Schaefer to retake the Multistate Pharmacy Jurisprudence Examination. He must pay a forfeiture of \$500 and costs of \$250.

Dated: April 7, 2010

http://online.drl.wi.gov/decisions/2010/ORDER 0000137-00004813.pdf

Community Home Medical Equipment LLC

– Distributor, Madison, WI

The Pharmacy Examining Board reprimanded Community Home Medical Equipment LLC for failing to maintain a security system for monitoring entry into a facility after hours. The security system is now operational. The Board ordered Community Home Medical Equipment to pay a forfeiture in the amount of \$1,000 and costs of \$160.

Dated: April 7, 2010

http://online.drl.wi.gov/decisions/2010/ORDER 0000135-00004811.pdf

Reedsburg Area Medical Center – Pharmacy, Reedsburg, WI

The Pharmacy Examining Board reprimanded Reedsburg Area Medical Center for providing false information to the Pharmacy Examining Board or its agent. The Pharmacy claimed to have a centrally monitored alarm system in the pharmacy, or in the immediate physical structure within which the pharmacy was located, when in actuality it did not have such an alarm system. The Board ordered Reedsburg Area Medical Center to pay a forfeiture of \$250 and costs of \$250.

Dated: April 7, 2010

http://online.drl.wi.gov/decisions/2010/ORDER 0000134-00004810.pdf

June 2010

Michael F. Jensen – Pharmacist, Stevens Point, WI

The Pharmacy Examining Board reprimanded Michael F. Jensen, R.Ph., for errors in preparing, checking, and dispensing a prescription, which occurred when he was the managing pharmacist. Jensen was the managing pharmacist when a consumer received two bottles, one labeled Keppra 250 mg and the other labeled Keppra 750 mg. In reality, both contained Keppra 750 mg. The Board ordered Jensen to pay a forfeiture of \$250 and costs of \$250.

Dated: June 7, 2010

 $\frac{http://online.drl.wi.gov/decisions/2010/ORDER}{0000246\text{-}00004998.pdf}$

DID YOU KNOW THAT YOU CAN ACCESS MOST INFORMATION ON THE DEPARTMENT OF REGULATION & LICENSING WEB SITE?

Visit the Department's Web site at:

www.drl.wi.gov

Send comments to: Webmaster@drl.state.wi.us

CHANGE OF NAME OR ADDRESS?

Please send changes to the Department. Confirmation of changes is not automatically provided. <u>WIS</u>. <u>STATS</u>. S. 440.11 ALLOWS FOR A \$50 PENALTY TO BE IMPOSED WHEN CHANGES ARE NOT REPORTED WITHIN 30 DAYS.

TELEPHONE DIRECTORY

To contact the Department, just dial (608) 266-2112, then follow the instructions for the service you need:

For renewal questions, say 'renewal'
For a new license including exam and education requirements, say 'licensing'
For complaint information, say 'complaint'
For legal questions or interpretations, say 'legal questions'
For exam administration, say 'exam'
For continuing education, say 'education'

For exam administration, say 'exam'
For continuing education, say 'education'
For your pin, say 'obtain pin'
For license verifications, say 'verify license'
For the agency staff directory, say 'staff directory'
For all other questions, say 'operator'

VERIFICATIONS

Verifications are now available online at www.drl.wi.gov/. On the Department Web site, please click on "Lookup a License". If you do not use the online system, all requests for verification of licenses/credentials must be submitted in writing. There is no charge for this service. Requests should be sent to the Department address or may be faxed to (608) 261-7083 - ATTENTION: VERIFICATIONS. Requests for endorsements to other states must be made in writing — please include \$10 payable to the Department.